DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Centinel Spine, Incorporated
% Mr. Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

July 31, 2015

Re: K150053
Trade/Device Name: STALIF C® and STALIF C-Ti™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: June 24, 2015
Received: June 24, 2015

Dear Mr. Eggleton:

This letter corrects our substantially equivalent letter of June 24, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Summary

Device Trade Name: STALIF C® and STALIF C-Ti™

Manufacturer:
Centinel Spine, Inc.
900 Airport Road, Suite 3B
West Chester, PA 19380

Contact:
Mr. John Parry
Development Manager
Phone: (484) 887.8813

Prepared by:
Mr. Justin Eggleton
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
jeggleton@mcra.com

Date Prepared: June 22, 2015

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: OVE

Primary Predicate: K142079, STALIF C®, STALIF C-Ti™

Reference Device: K142264, Amedica Valeo® Cage

Indications For Use:
The STALIF C® and STALIF C-Ti™ devices are intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space at one or two contiguous levels from the C2/C3 disc space to the C7/T1 disc space for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

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Summary of Technological Characteristics:
STALIF C® is a radiolucent intervertebral body fusion cage with unicortical cancellous bone screws. It is intended to be used as an IBF cage without supplementary fixation. The cross section profile of the STALIF C® is similar to that of the vertebral body endplate with central cavity that can be packed with autograft or allograft. STALIF C® is manufactured from either PEEK-OPTIMA® LT1 supplied by Invibio or Zeniva ZA PEEK supplied by Solvay per ASTM F2026 with titanium alloy screws (Ti6Al4V, ASTM F136) and X-ray marker wires manufactured from unalloyed Tantalum (ASTM F560). The STALIF C-Ti™ is identical to this design with a titanium plasma spray coating (CPTi per ASTM F1580) on the device endplates.

The purpose of the subject 510(k) was to expand the indications to allow for use in multilevel procedures (i.e., two contiguous levels).

Predicate Device:
The subject STALIF C® and STALIF C-Ti™ intervertebral body fusion devices are substantially equivalent to predicate STALIF C® and STALIF C-Ti™ (K142079) with respect to indications, design, function, and materials.

Substantial Equivalence:
STALIF C®, STALIF C-Ti™ and predicate STALIF C®, STALIF C-Ti™ devices are identical in design, material, and performance. A comprehensive clinical literature review was conducted to assess any additional safety concern for the use of this device (accounting for its integrated fixation features) at two cervical levels.

Performance Testing:
A comprehensive, clinical literature review and PearlDiver reimbursement data have been provided to investigate the risks and benefits associated with the use of the STALIF C® devices in multilevel cervical procedures. Additionally, cadaveric biomechanical testing was conducted to support substantial equivalence.

Conclusion:
The Centinel Spine STALIF C® and STALIF C-Ti™ have been modified to expand the indications to permit use in multilevel cervical procedures (i.e., one or two contiguous levels). The 510(k) demonstrates substantial equivalence to predicate devices.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150053

Device Name
STALIF C® and STALIF C-Ti™

Indications for Use *(Describe)*

The STALIF C® and STALIF C-Ti™ devices are intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space at one or two contiguous levels from the C2/C3 disc space to the C7/T1 disc space for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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